

### **REMARKS**

Reconsideration of this application is respectfully requested. Upon entry of this amendment, Claims 7 and 32 are presently pending. Claim 7 has been amended. No new matter has been added.

#### **Rejection under 35 U.S.C. §112, second paragraph.**

Claims 7 and 32 stand rejected under 35 U.S.C. 112, second paragraph, as indefinite, for the reasons stated on pages 2-3 of the Office Action.

The Office Action states that Claim 7 recites the limitation “the target polynucleotide in yeast” which lacks sufficient antecedent support in the preceding body or preamble of the claim. Claim 7 has been amended to more clearly recite that the claim encompasses a vector for delivery of large nucleic acids to a yeast target cell.

Applicants respectfully submit that the grounds for the rejection have been obviated by the amendments submitted in this communication. Withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

#### **Rejection under 35 U.S.C. §102(e).**

Claims 7 and 32 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Elledge et al. (US 6,828,093) for reasons stated on page 3-4 of the Office Action. Applicants respectfully traverse the rejection.

The Office Action states that Elledge et al. allegedly teaches recombinant vectors that contain two cyclization elements (i.e., lox sites), two selectable markers (kanamycin and Ampicillin) and a gene of interest that would necessarily contain some portions that are

homologous to the 5' and 3' regions of the gene. The Office Action further states that the gene of interest can be from AAV.

The Examiner has interpreted Claim 7 to mean that the first and second segments comprise homologous regions to a target polynucleotide such that the claims are directed to any vector comprising a first and second cyclization element, a first and second segment homologous to the 3' and 5' end of a target polynucleotide where the target polynucleotide is of a selected group of viruses such as AAV and that the limitation "in yeast" is of little moment. The Advisory Action further states that because the claims are directed to a product, a product with the same structural limitations anticipates regardless of intended use.

Applicants respectfully disagree. Claim 7 has been amended to more clearly reflect the invention which provides a recombinant cloning system which relies on homologous recombination to mediate the isolation, manipulation and delivery of large nucleic acid segments where homologous recombination occurs in a yeast cell based on the presence of a polynucleotide sequence homologous to a yeast target polynucleotide sequence. Applicants respectfully submit that Elledge et al. does not disclose or suggest a polynucleotide sequence homologous to a yeast target polynucleotide sequence which is a structural feature of Claim 7. The fact that the claims are directed to a vector for capture, cloning, manipulation, production and delivery of large nucleic acids to a yeast target cell is not merely an intended use, it necessitates that the vector comprises a polynucleotide sequence homologous to a yeast target polynucleotide sequence. The suggestion of such a polynucleotide sequence is lacking in Elledge et al.

For anticipation under 35 U.S.C. § 102, the reference "must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be

inherently present.” (MPEP §706.02). “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” Verdegaal Bros. v. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

As previously argued, the gist of the invention described in Elledge et al. is rapid cloning of a gene of interest into a vector having a desired regulatory element utilizing sequence-specific recombinase technology. Elledge generally describes a technique of using a univector construct, which contains a gene of interest and a sequence-specific recombinase target site, to transfer the gene of interest into an expression vector, which contains a sequence-specific recombinase target site located downstream of a regulatory element, in the presence of a recombinase. The end product is an combined expression construct having the gene of interest of the univector under the regulation of the regulatory element of the expression vector.

Elledge does not describe a combined expression construct that comprises a polynucleotide sequence homologous to a yeast target polynucleotide sequence for homologous recombination with a target polynucleotide in yeast. Applicants respectfully submit that the simple existence of an AAV gene in the expression construct of Elledge does not equate to description for “a first segment homologous to the 5' terminus of a target polynucleotide” and “a second segment homologous to the 3' terminus of the target polynucleotide,” with the target polynucleotide being a polynucleotide from AAV. Additionally, there is no mention in Elledge that the expression vector is capable of homologous recombination with the target polynucleotide in yeast. Thus Elledge not only lacks explicit description of the structural features of the invention as required for anticipation under 35 U.S.C. § 102(e).

Accordingly, Applicants respectfully submit that Elledge does not anticipate, nor does t  
render obvious, Claim 7 or 32. Withdrawal of the rejection under 35 U.S.C. § 102(e) is  
respectfully requested.

**CONCLUSION**

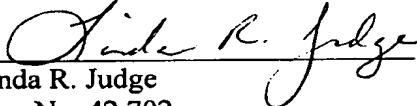
Applicants submit that the application is now in condition for examination on the merits.  
Early notification of such action is earnestly solicited. Should the Examiner have any  
suggestions to place the application in even better condition for allowance, Applicants request  
that the Examiner contact the undersigned representative at the telephone number listed below.

In light of the above, Applicants submit that this application is now in condition for  
allowance and therefore request favorable consideration. If any issues remain which the  
Examiner feels may be best resolved through a personal or telephonic interview, the Examiner is  
respectfully requested to contact Applicants' counsel, Linda R. Judge at (415) 836-2586.

Respectfully submitted,

**DLA Piper Rudnick Gray Cary US LLP**

Dated: 2/7/06

By   
Linda R. Judge  
Reg. No. 42,702

1200 Nineteenth Street, N.W.  
Washington, D.C. 20036-2412  
Telephone: (202) 861-3900  
Facsimile: (202) 223-2085